K132712

510(k) Summary of Safety and Effectiveness

Date Prepared: August 26, 2013

Applicant:
Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Brooklyn Park, MN 55428
Establishment Registration No. 2184009

Contact Person:
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NOV 19 2013

Trade Name: Affinity™ CP Centrifugal Blood Pump

Common Name: Centrifugal blood pump

Classification Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type

Classification: Class III, 21 CFR 870.4360

Product Code: KFM

Name of Predicate Device: Affinity™ CP Centrifugal Blood Pump with or without coatings – Model AP40 (K100631), Model BBAP40 (K111657), Model CBAP40 (K111658)

Sarns™ Centrifugal Pump with or without X-Coating (K112229)

Device Description

Affinity CP Centrifugal Blood Pumps are intended to be used in medical procedures requiring extracorporeal circulation circuits. The pump is designed to move blood by centrifugal force generated by a combination of a smooth rotating cone and low-profile impeller fins. Energy is

transferred from the pump in the form of pressure and velocity as the blood is driven toward the outlet port of the pump. The pump internal impeller magnetically couples to a drive motor. Magnetic coupling is used since it precludes the need for a shaft through the pump housing. The pump is supplied uncoated or coated.

This submission covers expanded indications for use for the pump when used with the Affinity CP Adapter – Model AP40AST. These updates will allow the Affinity CP Pump to couple with the Affinity CP Adapter and enable the pump to be operated with the Stöckert and Sorin, or Sarns and Terumo centrifugal pump systems. No changes are being made to Affinity CP Pump or its' performance specifications. The Affinity CP Adapter is a reusable non-sterile device. The use of the adapter does not require modification of the compatible systems.

Intended Use

The Affinity CP Centrifugal Blood Pump is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).

The Affinity CP Centrifugal Blood Pump is driven by the External Drive Motor or the Emergency Handcrank.

The Affinity CP Centrifugal Blood Pump is intended for use with Medtronic controllers or may be used with the Stöckert and Sorin centrifugal pump systems or the Sarns and Terumo centrifugal systems by attaching the Affinity CP adapter.

Comparison to the Predicate Device

The Affinity CP Centrifugal Blood Pump with the Affinity CP Adapter is substantially equivalent to the predicates outlined in the following comparison tables. There have been no changes to the pump or its' performance specification.

Device Name	**PREDICATE: Affinity CP Centrifugal Blood Pump (with or without coating)**	**PREDICATE: Sarns Centrifugal Pump**	**MODIFIED DEVICE: Affinity CP Centrifugal Blood Pump (with or without coating) used with Affinity CP Adapter**
510(k) Number	K100631 K111657 K111658	K112229	Modified device – subject of this 510(k)

Device Name	PREDICATE: Affinity CP Centrifugal Blood Pump (with or without coating)	PREDICATE: Sarns Centrifugal Pump	MODIFIED DEVICE: Affinity CP Centrifugal Blood Pump (with or without coating) used with Affinity CP Adapter
Indications for Use	The Affinity CP Centrifugal Blood Pump* *is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours). It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardio-pulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants). The Affinity CP Centrifugal Blood Pump is driven by the External Drive Motor or the Emergency Handcrank.	The Sarns Centrifugal Pump with or without X-Coating is a sterile, single use device, used as an extracorporeal blood pump for use in cardiopulmonary bypass procedures for up to 6 hours. The pump is intended for use with the Sarns Centrifugal Systems or may be used with Stöckert Centrifugal Pump Systems by attaching the Sarns Centrifugal Pump Adapter.	The Affinity CP Centrifugal Blood Pump* is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours). It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants). The Affinity CP Centrifugal Blood Pump is driven by the External Drive Motor or the Emergency Handcrank. The Affinity CP Centrifugal Blood Pump is intended for use with Medtronic controllers or may be used with the Stöckert™ and Sorin™ centrifugal pump systems or the Sarns™ and Terumo™ centrifugal systems by attaching the Affinity CP adapter.

* With or without coatings

Device Name	PREDICATE: Affinity CP Centrifugal Blood Pump (with or without coating)	PREDICATE: Sarns Centrifugal Pump	MODIFIED DEVICE: Affinity CP Centrifugal Blood Pump (with or without coating) used with Affinity CP Adapter
Contraindications	The Affinity CP Centrifugal Blood Pump is contraindicated for use as a cardiotomy suction device. This device, used for any other purposes than the intended use, is the responsibility of the user.	This device is contraindicated for use as a suction device.	The Affinity CP Centrifugal Blood Pump is contraindicated for use as a cardiotomy suction device. This device, used for any other purposes than the intended use, is the responsibility of the user.

Device Name	PREDICATE: Affinity CP Centrifugal Blood Pump (with or without coating)	MODIFIED DEVICE: Affinity CP Centrifugal Blood Pump (with or without coating) used with Affinity CP Adapter
Pump Functionality	Propels blood through the extracorporeal circuit via a combination of a smooth rotating cone and low-profile impeller fins	Same
Pump Operating Principle/ Technology	Energy is transferred from the pump in the form of pressure and velocity as the blood is driven toward the outlet port of the pump	Same
Housing Material	Polycarbonate	Same (pump and adapter)
Pump Motor Interface	Magnetic coupling	Same (pump and adapter)
Pump Prime Volume	40 mL	Same
Inlet/Outlet ID	9.5 mm (3/8 in)	Same
Maximum Operating Pressure	760 mm Hg (101 kPa)	Same
Maximum Flow Rate	10 L/min	Same
Maximum Outlet Pressure	700 mm Hg (93.3 kPa)	Same
Maximum Pump Speed	4000 rpm	Pump: Same Adapter: 3600 rpm
Uncoated and Coating Options	AP40: Uncoated Pump	Same

Device Name	PREDICATE: Affinity CP Centrifugal Blood Pump (with or without coating)	MODIFIED DEVICE: Affinity CP Centrifugal Blood Pump (with or without coating) used with Affinity CP Adapter
	BBAP40: Pump with Balance Biosurface CBAP40: Pump with Carmeda BioActive Surface	
Sterilization Method	Ethylene Oxide (EtO)	Pump: Same Adapter: Non-sterile
Compatible Systems	Medtronic Controller, External Drive Motor and Hand Crank	Pump: Same Adapter: Stöckert and Sorin centrifugal pump systems or Sarns and Terumo centrifugal systems as defined in the Instructions for Use

Summary of Performance Data

In-vitro testing was performed to demonstrate both substantial equivalence with the predicate devices and also to comply with user needs and safety and effectiveness requirements.

Testing supplied in the 510(k) Notification includes formal data collection, mechanical and performance verification, reliability verification, system verification, labeling and Instructions for Use (IFU) verification and validation tests.

The system verification and validation tests showed that the use of the adapter does not affect how a compatible system responds when the safety related RPM control response conditions are triggered. Additionally, the adapter does not decouple from the compatible system motor drives.

All testing passed by meeting the established requirements set forth for the use of the Affinity CP Adapter with Affinity CP Centrifugal Blood Pumps (with or without coatings).

Conclusion

The data included in this submission is sufficient to provide reasonable assurance that the Affinity CP Pump when used with the Affinity CP Adapter is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2013

Medtronic, Inc.
Medtronic Perfusion Systems
Lisa Stone, RAC
7611 Northland Drive
Brooklyn Park, MN 55428

Re: K132712
Trade/Device Name: Affinity CP Centrifugal Blood Pump (uncoated, Balance coated, Carmeda coated) Model AP40, Model BBAP40, Model CBAP40
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller Type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class III
Product Code: KFM
Dated: August 26, 2013
Received: August 29, 2013

Dear Ms. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

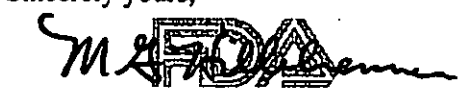
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K132712

Affinity™ CP Centrifugal Blood Pump (Model AP40)

Indications for use:

The Affinity™ CP Centrifugal Blood Pump is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).

The Affinity CP Centrifugal Blood Pump is driven by the External Drive Motor or the Emergency Handcrank.

The Affinity CP Centrifugal Blood Pump is intended for use with Medtronic controllers or may be used with the Stöckert™ and Sorin™ centrifugal pump systems or the Sarns™ and Terumo™ centrifugal systems by attaching the Affinity CP adapter.

Prescription Use X **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)